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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/570,126	06/12/2007	Thomas Roberts	GJE-1051XC1	7405
23557 7590 12/11/2008 SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO BOX 142950 GAINESVILLE, FL 32614-2950				
EXAMINER NOBLE, MARCIA STEPHENS				
ART UNIT		PAPER NUMBER		
1632				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/570,126

Applicant(s)

ROBERTS ET AL.

Examiner

MARCIA S. NOBLE

Art Unit

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-52 is/are pending in the application.
- 4a) Of the above claim(s) 27b-d and 34-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27a-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 February 2006 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB08)
Paper No(s)/Mail Date 9/28/2007.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Status of Claims

Claims 27-52 are pending.

Election/Restrictions

Applicant's election without traverse of Group 1 encompassing claims 27a-33 drawn to a mutant SV40 T antigen protein that lacks the ability to bind the Bub1 protein in the reply filed on 11/5/2008 is acknowledged.

Claims 27b-d and 34-52 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected subject matter, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/5/2008.

Claims 27a-33 are under consideration.

Sequence Compliance

The nucleotide sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825.

37 CFR 1.821(d) states: "[w]here the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO:" in the text of the description of claims,

even if the sequence is also embedded in the text or the description or claims of the patent application.

Figure 4a comprises amino acid sequences that lack sequence identifiers. Amending the specification to incorporate the appropriate SEQ ID NOS would be remedial.

Appropriate correction is required.

The absence of proper sequence listing did not preclude the examination on the merits however, **for a complete response to this office action, applicant must submit the required material for sequence compliance.**

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 27a-31 are rejected under 35 U.S.C. 102(b) as being anticipated by Stubal et al (Molecular and Cellular Biology 17(9):4979-4990, 1997; of record).

Stubdal et al discloses a mutant SV40 T antigen comprising a deletion of residues 89 to 97 (p. 4981, col 1, 1st full par, lines 13-15). Stubdal et al does not disclose that this SV40 T antigen lacks the ability to bind Bub1. However, the specification discloses a mutant SV40 T antigen with a deletion of residues 89-97. The specification teaches that this SV40 T antigen mutant is defective in binding Bub1 (p. 4, lines 19-20). Thus, structurally it is the same mutant SV40 T antigen disclosed by the specification. Therefore, inherently the mutant SV40 T antigen disclosed by Stubdal et

al lacks the ability to bind Bub1 and therefore discloses a mutant SV40 T antigen that lacks the ability to bind Bub1 as claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 27a and 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stubal et al (Molecular and Cellular Biology 17(9):4979-4990, 1997; of record), in further view of McKay et al (US Pat No. 5,270,191 date of patent: 12/14/1993; of record).

Stubdal et al teaches a mutant SV40 T antigen comprising a deletion of residues 89 to 97 (p. 4981, col 1, 1st full par, lines 13-15). Stubdal et al does not specifically

teach that this SV40 T antigen lacks the ability to bind Bub1. However, the specification discloses a mutant SV40 T antigen with a deletion of residues 89-97. The specification teaches that this SV40 T antigen mutant is defective in binding Bub1 (p. 4, lines 19-20). Thus, structurally it is the same mutant SV40 T antigen disclosed by the specification. Therefore, the mutant SV40 T antigen taught by Stubdal et al lacks the ability to bind Bub1 because the SV40T antigen taught by Stubdal et al is structurally the same as the mutant disclosed by the specification and therefore had the same properties as the mutant disclosed by the specification. Stubal et al also teaches an expression plasmid encoding the above mutation and a means of expressing said plasmid in cultured cells (p. 4980, col 1, par 3, line 1 to col 2, line 4).

Stubdal et al does not specifically teach that the SV40 T antigen protein comprises a U19 mutation or is a temperature-sensitive large T antigen. However, McKay et al teaches a construct encoding a U19 mutation and tsA58 mutation a SV40 T antigen protein (Figure 2B, col 2, lines 26-29). McKay et al teaches that temperature sensitive variants to the SV40 T antigen are known and can be used in developing other SV40T antigen variants (col 7, lines 42-44). McKay et al also teaches a means of developing a SV40T antigen with a U19 mutation (col 15, lines 26-40). McKay et al teaches that the use of U19 and tsA58 mutations increase the immortalization efficiency and thermolability of the SV40 T antigen protein (col 7, lines 24-26). Therefore, McKay et al teaches a motivation to include U19 and tsA58 mutations in an SV40T antigen mutant because U19 and tsA58 mutations will increase the immortalization efficiency and thermolability of the SV40 T antigen protein.

The combination of prior art cited above in all rejections under 35 U.S.C. 103 satisfies the factual inquiries as set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). Once this has been accomplished the holdings in KSR can be applied (*KSR International Co. v. Teleflex Inc. (KSR)*, 550 U.S. ___, 82 USPQ2d 1385 (2007): "Exemplary rationales that may support a conclusion of obviousness include: (A) Combining prior art elements according to known methods to yield predictable results; (B) Simple substitution of one known element for another to obtain predictable results; (C) Use of known technique to improve similar devices (methods, or products) in the same way; (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results; (E) "Obvious to try" - choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art; (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention."

In the present situation, rationales A, C and G are applicable. It would have been obvious to an artisan of ordinary skill at the time the invention was made to modify the SV40 T antigen mutant, taught by Stubdal et al, to incorporate a temperature sensitive mutation and U19 mutation, as taught by McKay using the methods taught by Stubdal et al and McKay et al to predictably yield a SV40 T antigen comprising a deletion or

mutation in amino acids 89-97, a U19 mutation, and a temperature sensitive mutant with a reasonable expectation of success in order to determine the effective of temperature sensitivity and the U19 activity on Bub 1. Thus, the teachings of the cited prior art in the obviousness rejection above provide the requisite teachings and motivations with a clear, reasonable expectation. The cited prior art meets the criteria set forth in both Graham and KSR.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 33 recites the limitation "the temperature-sensitive large T antigen" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCIA S. NOBLE whose telephone number is (571)272-5545. The examiner can normally be reached on M-F 9 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Deborah Crouch/
Primary Examiner, Art Unit 1632

Marcia S. Noble